[10121/01601]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	James F. McGUCKIN, Jr.
Serial No.	:	09/697,306 ✓
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For	:	SURGICAL APPARATUS AND METHOD
Group Art Unit	:	3761
Examiner	:	Glenn K. Dawson

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Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

In support of the Notice of Appeal filed February 27, 2004, and pursuant to 37 C.F.R. § 1.192, appellee presents in triplicate his appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 36 - 48 in the final Office Action dated November 7, 2003 as clarified in the Advisory Action mailed February 17, 2004. The appealed claims are set forth in the attached Appendix A.

1. Real Party in Interest

This application is subject to an exclusive license from the inventor to Boston Scientific Corporation of Natick, Massachusetts, the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 36 - 51 are pending.

Claims 36 - 48 were rejected in the final Office Action and are involved in this appeal. Claims 49 - 51 have been allowed.

4. Status of Amendments

All amendments filed by the appellee have been entered. None were submitted after the Advisory Action.

5. Summary of the Invention

The invention is directed to an apparatus for resecting tissue within a body lumen, comprising an operating capsule selectively coupleable to a flexible endoscope, the operating capsule, when in an operative position, being located within a body lumen adjacent to a selected portion of tissue to be resected, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly and a tissue grabber drawing the selected portion of tissue into the cutting zone, wherein the suturing assembly fastens together portions of tissue

adjacent to the selected portion of tissue.

6. Issues

I. Whether claims 36 - 38, 40 - 44 and 46 - 48 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,395,030 to Kuramoto ("Kuramoto").

II. Whether claims 36 - 48 are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,389,98 to Tsuruta ("Tsuruta") in view of U.S. Patent No. 5,562, 694 to Sauer ("Sauer") and in further view of German Patent Publication No. 4,006,673 to Kessel ("Kessel").

7. Grouping of Claims

Claims 36 - 43 stand together and claims 44 - 48 stand together.

8. Argument

I. The Rejection of Claims 36 - 38, 40 - 44 and 46 - 48 Under 35 U.S.C. § 102(e) as Anticipated by U.S. Patent No. 5,395,030 to Kuramoto ("Kuramoto") Should be Reversed.

In the Final Office Action, the Examiner asserted that Kuramoto shows an endoscopic stapler having a capsule with a stapling mechanism and a cutter that may be inserted into the large intestine through the anus. The Examiner also stated that Kuramoto discloses an endoscope that is placed inside the capsule and extends through the shaft to the operating handle, which also includes grasping forceps that pull the tissue into the location between the stapler and

the anvil.

Claim 36 recites a resection apparatus comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of lumenal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" and "*a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue.*"

The Examiner stated that the grasping forceps of Kuramoto acts to pull tissue into the location between the anvil and the stapler. However, it is respectfully submitted that Kuramoto shows no tissue grabber as claimed. Specifically, the Examiner cited the description of Fig. 3 of Kuramoto in addition to that in Fig. 27 in support of his contention that Kuramoto shows such a tissue grabber. However, it is respectfully submitted that the embodiment of Fig. 3 is quite different from that of Fig. 27 and that the device of Fig. 3 includes no graspers. Nor would any graspers be useful in this application as the device of Fig. 3 is for use in an open surgical full circle anastomosis procedure wherein a surgeon applies a suture manually via an incision to

purse string severed ends of the large intestine around the tubular shaft 23 (Specification, col. 8, lines 30 - 40 and Fig. 3B) thereby drawing the tissue between the anvil 6 and the stapling member 4 manually.

Furthermore, the device of Fig. 27 includes a holding forceps 150 used only to manipulate and hold the tip of an anvil shaft. (Specification, col. 17, lines 39-41). This forceps 150 is completely incompatible with the function of drawing tissue between the anvil and the stapling mechanism as will be described below. Specifically, the anvil of this embodiment is separable from the stapling member so that it may be manually positioned on an opposite side of a surgical site at which a full circular section of the intestine has been removed. That is, a portion of the intestine is removed through an open surgical procedure and the anvil is placed in one of the severed ends of the intestine while the stapling mechanism is positioned in the other severed end. As shown in Fig. 23, a main unit 136 is first inserted into the stomach 110 and an auxiliary unit 141 including the anvil 146 is deployed, passed into the duodenum 111 and manipulated until it abuts the diseased tissue. The anvil shaft 147 is then used to pierce the wall of the duodenum 111 and the wall 113 of the stomach 110. The insertion section 142 is then disconnected from the anvil 146 which is left in position on the walls 113 and 114 of the stomach 110 and the duodenum 111, as shown in Fig. 24. (Specification, col. 17, lines 23 - 34). Thereafter, the main unit 136 is positioned near the tip of the anvil shaft 147 and the holding forceps 150 is deployed from the hole 140 to grasp the anvil shaft 147 (See, Fig. 22). The holding forceps 150 are then withdrawn into the hole 140 to draw the anvil shaft 147 thereinto. (Specification, col. 17, lines 35

- 42). Thus, the holding forceps 150 are used only to draw the anvil back into connection with the housing 138 and, after the anvil shaft 147 is received within the hole 140, the holding forceps 150 are no longer deployable to grasp tissue or for any other purpose.

In response to the Applicants Arguments, the Examiner stated that:

> the flexible forceps of Kuramoto could easily be directed to grasp a full thickness fold of tissue and pull it into a cutting zone or the space between the stapler and the anvil, even through this is not shown, because as shown in Fig. 25, the forceps could be directed to a position misaligned with the anvil projection147 and could grasp a fold of tissue with its jaws.

(Office Action, page 4).

Initially, it is respectfully submitted that there is no showing or suggestion of any mechanism for directing the forceps 150 to a position misaligned with the anvil projection 147 and that this would completely frustrate the only intended operation of these forceps 150 - i.e., grasping the anvil projection 147 and drawing it into the hole 140 from which the forceps 150 are deployed.

Furthermore, as described above, the holding forceps 150 are deployable only when the anvil 146 remains unconnected to the housing 138 as the forces 150 are deployable only through the hole 140 into which the anvil projection 147 is drawn. Under these circumstances, there is no cutting zone formed the anvil 146 and the stapling mechanism and predicting the results of the use of the forceps 150 to grasp tissue in a way neither shown, suggested or even contemplated in Kuramoto to pull tissue to which the anvil 146 is connected while the anvil 146 is not connected to the housing 138 is purely speculative and could in no way be said to assist in performing the

function of the device of Kuramoto. In the Advisory Action, the Examiner stated that the recitations in regard to the tissue grabber described above are merely functional and include no structural limitations. However, as the graspers 150 of Kuramoto are mounted in a manner wholly structurally incompatible with the drawing of tissue between the anvil and the stapling mechanism, it is respectfully submitted that these recitations do in fact place structural limitations on the recited apparatus and system which limitations are clearly not met by Kuramoto.

Thus, the applicant respectfully submits that Kuramoto neither shows nor suggests a resection apparatus comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of lumenal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" and "*a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue*," as recited in claim 36.

It is therefore respectfully submitted that claim 36 is not anticipated by Kuramoto and that

this rejection should be withdrawn. Because claims 37, 38 and 40 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Similarly, claim 44 recites a system for resecting tissue where "*a flexible grasping mechanism extending through the sheath for grasping a full thickness fold of tissue including a portion of tissue selected for resectioning and drawing grasped fold of tissue into a space between the stapling mechanism and the anvil.*" It is respectfully submitted that claim 44 is allowable for the same reasons stated above in regard to claim 36. Because claims 46 - 48 depend from and, therefore, include all of the limitations of claim 44, it is respectfully submitted that these claims are also allowable.

II. The Rejection of Claims 36 - 48 Under 35 U.S.C. § 103 Over Tsuruta In View of Sauer and Kessel Should Be Reversed

The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone and an internal endoscope. The Examiner further stated that Sauer shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention. Furthermore, the Examiner stated that Kessel discloses forceps with an internal endoscope.

Claim 36 has recites "*a flexible member extending proximally from the operating capsule*

to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle." Unlike the apparatus of claim 36, Tsuruta shows various rigid surgical instruments which are inserted into body cavities *via incisions made therein.* (Col. 2, lines 44-46). Specifically, Tsuruta states that the disclosed stapling member operates as follows: "A body wall or the like is incised. The stapling member 5 and the insertion section 2 are inserted into the body cavity through the incision... (Specification, col. 10, lines 7 - 9). "An incision is formed in a body wall such as the abdominal wall. The stapling member 5 and the insertion section 2 are inserted into a body cavity through the incision." (Specification, col. 26, lines 42 - 46). "To insert the stapling member 5 into a body cavity, it is closed and then inserted into the trocar 314." (Specification, col. 33, lines 28 - 30). It is respectfully submitted therefore that no such flexible member extending "*through the body and out a natural body orifice to the control handle,*" as recited in claim 36 is shown or suggested by Tsuruta.

In the Advisory Action, the Examiner stated that one skilled in the art would have had no problem making a rigid stapler flexible using the recited flexible components. Initially, it is respectfully submitted that this statement indicates that the Examiner is viewing the invention using impremissible hindsight. That is, the question is not what one skilled in the art would have done if someone asked him to make the current invention by modifying a prior device using a list of parts derived from this application. Rather, does the prior art alone suggest doing what the applicant has done.

Specifically, as the Federal Circuit has made clear, the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). More specifically, *it is improper to modify a prior art reference unless the prior art suggests the desirability of the specific modification.* In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

Thus, it is respectfully submitted that the motivation for the combination proposed by the Examiner is impermissibly derived at least in part from the applicant's own specification and that this rejection should, therefore, be reversed.

Furthermore, it is respectfully submitted that Tsuruta not only does not describe any graspers grasping tissue in conjunction with its many embodiments, it specifically states that its stapler allows surgeons "to gather tissues a and b, *without using forceps*." (Specification, col. 22,

lines 20 - 22). That is, the staples themselves are used to draw portions of tissue together so that separate forceps are not needed. (See, specification, col. 23, lines 14 - 29). Tsuruta discloses forceps only for grasping thread guiding needles 225. (Specification, col. 27, lines 29 - 36). Thus, it is respectfully submitted that Tsuruta teaches away from any modification which would add such a grasper to its device as it has been designed to eliminate the need for the device.

The Examiner stated in the Advisory Action that "Tsuruta, while stating that forceps are not required, would be enhanced by providing such to make the device more adaptable and therefore better equipped to be more useful in different situations." Applicant respectfully disagrees. In fact, the inventor of Tsuruta thought it advantageous that his device did not include graspers and the Examiner has conceded that this is true. This statement seems to indicate that the Examiner believes the inventor did not know as well as he what would be useful or advantageous for the device he had invented. In any case, whether the Examiner is correct about the inclusion of graspers in the device of Tsuruta is immaterial as it is what is taught in the reference that is at issue here. And Tsuruta clearly teaches away from the inclusion of graspers in the device. Thus, it is respectfully submitted that, in ignoring these teachings of Tsuruta, the Examiner has engaged in an impermissible hindsight reconstruction of the invention.

Although the Examiner stated that Tsuruta discloses a flexible endoscopic stapler. (col. 34, lines 6-15), Tsuruta merely states that "the insertion section of the stapler can be either rigid or flexible" without disclosing any further details of the construction of the device. (col. 34, lines 6-7). A simple statement that an insertion section of a device including drive mechanisms for

various mechanisms (stapler, anvil/stapler moving mechanisms, etc.) may be either flexible or rigid is insufficient disclosure to enable one of skill in the art to make such a device operable and flexible. For example, Tsuruta does not disclose the flexible support structure and the mechanisms involved in transmitting manipulations by the user of the stapler from the control handle to the stapler along a flexible instrument - and certainly does not teach or suggest the structure necessary to arrive at a solution which would enable the device to be flexible enough to travel through a body lumen from a naturally occurring body orifice as required in claim 36. It is respectfully submitted that, since Tsuruta fails to sufficiently disclose a flexible instrument, this reference is insufficient to support the rejection.

Similarly, Sauer shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is locatable entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a *flexible* endoscope. Specifically, Sauer states that endoscopic procedures involve "incising through body walls for examining, viewing and/or operating on various bodily organs or structures" with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is not flexible as that term is used in this application and includes no "flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural

body orifice to the control handle," as recited in claim 36. Thus, it is respectfully submitted that both Tsuruta and Sauer are designed for use in conjunction with open surgery and are unsuitable to extend "through the body and out a natural body orifice to the control handle," as recited in claim 36.

The Examiner cites Kessel since it discloses forceps with an internal endoscope. That reference, however, has no relevance to surgical stapling and also shows a body lumen being accessed via an incision. Thus, it is respectfully submitted that Kessel fails to cure the above-noted deficiencies in Tsuruta and Sauer.

For these reasons, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either show or suggest an apparatus for resecting tissue within a body lumen, comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of lumenal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" as recited in claim 36.

It is therefore respectfully submitted that claim 36 is not rendered obvious by Tsuruta, Sauer and Kessel either taken alone or in combination and that this rejection should be

withdrawn. Because claims 37 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Similarly, claim 44 recites "*an operating head including a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of lumenal tissue is maintained, wherein the anvil and the stapling mechanism are permanently coupled to one another," in combination with "*a flexible grasping mechanism extending through the sheath for drawing tissue into a space between the stapling mechanism and the anvil.*"

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either shows or suggests a system including "*a flexible endoscope*" and "an operating head including *a coupling structure for selectively coupling to the endoscope*," as recited in claim 44.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Therefore, at least for these reasons, it is respectfully submitted that all of the presently

pending claims are allowable. Appellee respectfully requests that the Board overturn the Examiner's rejection of these claims.

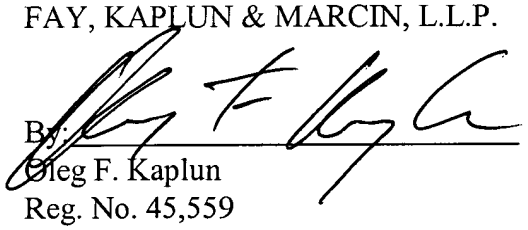
9. Conclusions

For the reasons set forth above, the appellee respectfully requests that the Board reverse the final rejections of claims 36 - 48 by the Examiner under 35 U.S.C. §§ 102 and 103, and indicate that these claims are allowable along with currently allowed claims 49 - 51.

Respectfully submitted,

FAY, KAPLUN & MARCIN, L.L.P.

Date: April 26, 2004

By: 
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